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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,353	03/07/2005	Qing Yang	F-8566	8302
28107 7590 11/12/2009 JORDAN AND HAMBURG LLP 122 EAST 42ND STREET SUITE 4000 NEW YORK, NY 10168				
EXAMINER				
NEGIN, RUSSELL SCOTT				
ART UNIT		PAPER NUMBER		
1631				
MAIL DATE		DELIVERY MODE		
11/12/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/523,353

**Applicant(s)**

YANG, QING

**Examiner**

RUSSELL S. NEGIN

**Art Unit**

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 53-70 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 53-70 is/are rejected.
- 7) ☒ Claim(s) 53 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 24 August 2009 has been entered.

### ***Comments***

Claims 53-70 are pending and examined in the instant Office action.

As explained below, it is noted that applicant has overcome the 35 U.S.C. 101 rejection; applicant has done so by the addition of the final line to claim 53. Consequently, the phrases "using a computer" on lines 6, 17, 20, 23, and 25 of claim 53 are unnecessary.

### ***Withdrawn Rejections***

The rejections of claims 53-70 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter are withdrawn in view of amendments filed to the instant set of claims on 24 August 2009.

The rejections of claims 53-70 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement are withdrawn in view of further consideration of the methods described on pages 3-5 of the specification.

The rejections of claims 53-70 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement are withdrawn in view of amendments to the instant set of claims on 24 August 2009.

### ***Claim Objections***

The following objections are NEWLY applied:

Claim 53 is objected to because of the following informalities:

Lines 10-11 of instant claim 53 recites " $\sigma_1$  is an ***estimating an*** initial delay value..." The line should read " $\sigma_1$  is an ***estimate of an*** initial delay value..."

Line 22 of instant claim 53 recites "***hermatocrit***," which should read "***hematocrit***."

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

#### **INDEFINITENESS**

The following rejections are reiterated with NEW grounds added:

Claims 53-70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 53 recites the limitation "said estimated and optimized TISSUE mean transit time and dispersion ( $t_2$ ,  $\alpha_2$ ,  $\sigma_2$ ) values" in lines 25-26. There is insufficient antecedent basis for this limitation in the claim. While estimated and optimized mean transit time and dispersion values are recited earlier in claim 53, nowhere is it required that these intended antecedent bases are to be applied solely to biological tissues.

Line 30 of claim 53 and lines 6-7 of claim 70 recite "quantitative said blood perfusion indices." While "said blood perfusion indices" has antecedent basis in line 2 of claim 53, the phrase "quantitative said blood perfusion indices" does not make grammatical sense. However, if corrected to "said quantitative blood perfusion indices," while now making grammatical sense, there is no antecedent basis requiring the blood perfusion indices to be QUANTITATIVE blood perfusion indices.

Claim 53 is additionally indefinite because it is not clear from the claim itself as to how to execute step d (using a computer to optimize said mean transit time and dispersion ( $t_2$ ,  $\alpha_2$ ,  $\sigma_2$ ) values using a least squares method). While claim 53 is enabled and fully described using the mathematical techniques clearly outlined on pages 3-5 of the specification, the claim itself should clearly recite the specific mathematical techniques utilized for the estimation and optimization in order for claim 53 to be fully definite.

The term "late arrival contrast agent peak" in claim 57 is a relative term which renders the claim indefinite. The term "late arrival" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not known as to relative to what quantity a late arrival qualifies as being late.

Claim 61 recites the limitation "said estimated and optimized TISSUE mean transit time and dispersion ( $t_2$ ,  $\alpha_2$ ,  $\sigma_2$ ) values" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. While estimated and optimized mean transit time and dispersion values are recited earlier in claim 53, nowhere is it required that these intended antecedent bases are to be applied solely to biological tissues.

The term "small lumen" in claim 66 is a relative term which renders the claim indefinite. The term "small lumen" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not known as to relative to what quantity a small lumen becomes small.

The term "more robust fitting process" in claim 66 is a relative term which renders the claim indefinite. The term "more robust" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not known as to relative to what level of robustness a "robust" fitting process becomes *more* robust.

Claim 66 recites the limitation "said simulated  $AIF_i(t)$ " in lines 3-4. There is insufficient antecedent basis for this limitation in the claim. While  $AIF_i(t)$  is recited earlier in the claim, a SIMULATED  $AIF_i(t)$  is not recited.

Claim 66 recites the limitation "said measured  $AIF_i(t)$ " in line 4. There is insufficient antecedent basis for this limitation in the claim. While  $AIF_i(t)$  is recited earlier in the claim, a MEASURED  $AIF_i(t)$  is not recited.

### ***Response to Arguments***

Applicant's arguments filed 24 August 2009 have been fully considered but they are not persuasive.

Applicant argues that the amendments overcome the rejections of record. However, for the 35 U.S.C. 112 indefiniteness rejections which are reiterated from the previous Office action on claims 57 and 66, no amendments were filed on claims 57 and 66. Consequently, these 35 U.S.C. 112 rejections are reiterated.

### ***Conclusion***

No claim is allowed.

Instant claims 53-70 are free of the prior art because the prior art does not teach or suggest the specific mathematical relations recited and the comparison of estimated and optimized comparisons of simulated and measured concentration profiles.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the

central PTO Fax Center. The faxing of such pages must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Negin, whose telephone number is (571) 272-1083. The examiner can normally be reached on Monday-Friday from 8:30am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Marjorie Moran, Supervisory Patent Examiner, can be reached at (571) 272-0720.

Information regarding the status of the application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information on the PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Russell S. Negin/  
Examiner, AU 1631  
30 October 2009